



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the Federal Register of June 11, 2010, FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products," which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on these draft and revised draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance recommendations.

Submit electronic comments on the draft product-specific BE recommendations to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kris André, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 1615, Silver Spring, MD 20993-0002, 240-402-7959.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the Federal Register of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products" which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft

recommendations are posted on FDA's Web site and announced periodically in the Federal Register. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the Federal Register. FDA considers any comments received, and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the Federal Register on April 2, 2014 (79 FR 18561). This notice announces draft product-specific recommendations, either new or revised, that are posted on FDA's Web site.

## II. Drug Products for Which New Draft Product-Specific

### BE Recommendations are Available

FDA is announcing the availability of a new draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

Table 1.--New Draft Product-Specific BE Recommendations for Drug Products

|   |   |
|---|---|
| A | Alogliptin benzoate                                     |
|   | Alogliptin benzoate; Metformin hydrochloride (HCl)      |
|   | Alogliptin benzoate; Pioglitazone HCl                   |
|   | Amoxicillin (multiple reference listed drugs)           |
|   | Atenolol; Chlorthalidone                                |
| C | Canagliflozin   |
|   | Carbidopa   |
|   | Carbinoxamine maleate                                   |
|   | Cefixime  |
|   | Colestipol HCl  |
|   | Crizotinib  |
| D | Daunorubicin citrate                                    |
|   | Diflorasone diacetate                                   |
|   | Dimethyl fumarate                                       |
|   | Diphenhydramine HCl                                     |
|   | Doxycycline (multiple reference listed drugs)           |
|   | Doxylamine succinate; Pyridoxine HCl                    |
| E | Esomeprazole strontium                                  |
|   | Ethinyl estradiol; Levonorgestrel and Ethinyl estradiol |
|   | Ethinyl estradiol; Norethindrone acetate                |
| F | Fosfomycin tromethamine                                 |
| G | Gentamicin sulfate                                      |
| H | Hydromorphone HCl                                       |
| L | Lanreotide acetate                                      |
|   | Linagliptin; Metformin HCl                              |
|   | Lomustine   |

|   |   |
|---|---|
| M | Menthol; Methyl salicylate                                    |
|   | Metformin HCl; Sitagliptin phosphate                          |
| O | Ospemifene  |
|   | Oxcarbazepine   |
| P | Paroxetine mesylate   |
|   | Promethazine (multiple reference listed drugs and strengths)  |
|   | Propranolol HCl   |
| R | Ropinirole HCl  |
| S | Sucralfate (multiple reference listed drugs and dosage forms) |
| T | Tacrolimus  |
| Z | Zolmitriptan  |

### III. Drug Products for Which Revised Draft Product-Specific

#### BE Recommendations are Available

FDA is announcing the availability of a revised draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

Table 2.--Revised Draft Product-Specific BE Recommendations for Drug Products

|   |  |
|---|--|
| D | Dronedarone HCl                              |
|   | Duloxetine HCl                               |
| E | Ergocalciferol                               |
|   | Esomeprazole magnesium                       |
| F | Fluorouracil                                 |
| H | Hydrochlorothiazide; Moexipril HCl           |
| I | Imatinib mesylate                            |
| L | Lansoprazole                                 |
| M | Mesalamine (multiple reference listed drugs) |
| N | Nevirapine                                   |
|   | Nilotinib HCl monohydrate                    |
| P | Pentosan polysulfate sodium                  |

For a complete history of previously published Federal Register notices related to product-specific BE recommendations, please go to <http://www.regulations.gov> and enter Docket No. FDA-2007-D-0369.

These draft and revised draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These guidances represent the Agency's current thinking on product-specific design of BE studies to support ANDAs. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An

alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

#### IV. Comments

Interested persons may submit either electronic comments on any of the specific BE recommendations posted on FDA's Web site to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. The guidances, notices, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

#### V. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: July 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.